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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,724	02/06/2001	Steven M. Ruben	PZ011	2764

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HUMAN GENOME SCIENCES INC  
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ROCKVILLE, MD 20850

EXAMINER
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LY, CHEYNE D

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 08/22/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/776,724

Applicant(s)

RUBEN ET AL.

Examiner

Cheyne D Ly

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

The art unit designated for this application has changed. Applicants(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

#### ***Election/Restrictions***

The inventions are distinct, each from the other because of the following reasons:

Restriction to one of the following inventions is required under 35 U.S.S. 121:

- I. Claims 1 – 10, and 21, drawn to an isolated nucleic molecule in class 536, subclass 23.1. If this Group is elected, then the below summarized sequence election is required.
- II. Claims 11 and 12, drawn to polypeptide in class 530, subclass 300. If this Group is elected, then the below summarized sequence election is required.
- III. Claim 13, drawn to an antibody in class 424, subclass 130.1. If this Group is elected, then the below summarized sequence election is required.
- IV. Claims 14 – 16, drawn to a method of making an isolated polypeptide in class 435, subclass 69.1. If this Group is elected, then the below summarized sequence election is required.
- V. Claim 17, drawn to a method for preventing, treating, or ameliorating a medical condition, comprising administering to a mammalian subject a therapeutically effective amount of a polypeptide or polynucleotide in class 514, subclasses 2 and 44. If this Group is elected, then the below summarized sequence election is required. Also, if this Group is elected then the below summarized specie election is required.

- VI. Claim 18, drawn to a method of diagnosing a pathological condition or a susceptibility to a pathological condition in a subject based on the presence or absence of a polynucleotide mutation in class 435, subclass 6. If this Group is elected, then the below summarized sequence election is required.
- VII. Claim 19, drawn to a method of diagnosing a pathological condition or a susceptibility to a pathological condition in a subject based on the presence or amount of expression of the polypeptide in class 435, subclass 7.1. If this Group is elected, then the below summarized sequence election is required.
- VIII. Claim 20 and 23, drawn to a method for identifying a binding partner to the polypeptide in class 435, subclass 7.1. If this Group is elected, then the below summarized sequence election is required.
- IX. Claim 22, drawn to a method for identifying an activity in a biological assay in class 435, subclass 7.1. Group is elected, then the below summarized sequence election is required.

**Sequence Election Requirement Applicable to All Groups:**

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid/polypeptide sequence, the Applicants must further elect a single amino acid/polypeptide sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic sequence (See MPEP § 803.04). It is noted that the multiple of sequence submissions for examination has resulted in an

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undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic sequences effectively impossible to reasonably implement.

MPEP § 803.04 states:

Nucleotides sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction and not a specie election requirement.

#### **SPECIE ELECTION REQUIREMENT FOR GROUP V:**

This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A: a second component, which is a polypeptide

Specie B: a second component, which is a polynucleotide

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Group V is generic. The species are distinct due to the distinct usages of polynucleotide and polypeptide. Individually, these distinct species are used in various methods for the treatment of a medical condition. For example, in the case of human secreted proteins, polynucleotides or polypeptides are used for preventing, treating, or ameliorating a

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medical condition by administering to a mammalian subject a therapeutically effective amount of the polypeptide.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions of Groups [I, V (polynucleotide specie), and VI]; [II, IV, V (polypeptide specie), VII, VIII and IX]; and [III] are distinct inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups I, V (polynucleotide specie) and VI, the critical feature is a nucleic acid molecule. For Groups II, IV, V (polypeptide specie), VII, VIII and IX, the critical feature is a polypeptide molecule. For Group III, the critical feature is an antibody. Further, it is acknowledged that various processing steps may cause a peptide of

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Groups II, IV, V (polypeptide specie), VII, VIII and IX to be directed as to its synthesis by a polynucleotide set forth in the method of Group I (polynucleotide specie), however, the completely separate chemical and entity types of the inventions of the polynucleotide and polypeptide support the undue search burden if they were examined together. Additionally, polynucleotide, polypeptide and antibody have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being search separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the three Groupings: [I, V (polynucleotide specie), and VI]; [II, IV, V (polypeptide specie), VII, VIII and IX]; and [III] are independent and/or distinct invention types for restriction purposes.

Inventions in Groups I, V (polynucleotide specie) and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case of human secreted proteins, an isolated nucleic acid Group I may be utilized in the distinct usages as needed in Group V (polynucleotide), which is a method for preventing, treating or ameliorating a medical condition. As needed in Group VI, which is a method for diagnosing a pathological condition or a susceptibility to a pathological condition. Alternatively, a polynucleotide molecule could be

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used to generate an antisense oligonucleotide for RNA interference studies, for example. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

Inventions in Groups II, IV, V (polypeptide specie), VII, VIII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case of human secreted proteins, an isolated polypeptide of Group II may be utilized in the distinct usages as needed in Group IV, which is a method for making an isolated polypeptide. As in Group V (polypeptide), which is a method for preventing, treating or ameliorating a medical condition. As needed in Group VII, which is a method for diagnosing a pathological condition or a susceptibility to a pathological condition. As needed in Group VIII, which is a method for identifying a protein-binding partner. As needed in Group IX, which is a method for identifying an activity in a biological assay. Alternatively, a polypeptide molecule could be used to quantify a protein's affinity for another protein through competitive binding assays. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.



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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

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Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly  
August 19, 2002

*Ardin H. Marschel*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER